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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/859,384	05/18/2001	Isabelle Nonotte	016800-444	3201

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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 05/07/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/859,384

Applicant(s)

NONOTTE ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 22-92 are pending. The Amended filed 3/18/03, Paper No. 9, cancelled claims 1-21 and added claims 22-92, and amended page 1 of the specification. The Supplemental Amendment filed 4/17/03, Paper No. 10, amended claims 22-35, 37 and 85.

Response to Arguments

Applicant's arguments with respect to claims 22-92 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments and amendment to the claims filed 3/18/03, Paper No. 9, and the supplemental amended to the claims filed 4/17/03, Paper No. 10, are sufficient to overcome the 35 USC 112 rejections in the previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-25, 27-28, 33-34, 59-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of manganese being the only active ingredient for treating wrinkles and fine lines is new and was not recited in the instant specification. Furthermore, all of the instant exemplifications require an antioxidant, which is an active ingredient that treats wrinkles.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 23, 29, 31, 32, 41, 49, 50, 52-54, 55, 71-74 rejected under 35

U.S.C. 102(b) as being anticipated by Murad (5,804,594).

Murad teaches pharmaceutical compositions and methods for improving wrinkles and other skin conditions. Exemplified is a tablet for oral administration comprising 2.8% manganese ascorbate and 0.5% vitamin A palmitate. See title and Col. 10, line 22-Col. 11, line 15.

The Examiner respectfully points out that for the purposes of searching for and applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to comprising. If an applicant contends that additional steps or material in the prior art are excluded by the recitation of “consisting essentially of”, applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention. See MPEP 2111.03.

The claims are directed to a method of applying a composition comprising manganese or a salt thereof and a carrier to the skin. Any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the

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prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product. The prior art teaches oral administration of compositions containing the same components as instantly claimed, which would inherently influence calcium channels in contractile fibers to relax and/or slacken cutaneous and/or subcutaneous tissue, as instantly claimed. Applicant has not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as instantly claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26, 39, 40, 42, 43, 44, 50, 51, 58, 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad et al. as applied to claims 22, 23, 29, 31, 32, 41, 49, 50, 52-54, 55, 71-74 above.

The instant invention is directed toward a method of administering to a person in need of relaxing and/or slackening cutaneous and/or subcutaneous tissue, a composition comprising an effective amount of manganese and/or a salt thereof and a cosmetically acceptable vehicle. The instant invention is further directed toward a composition consisting essentially of manganese, alverine or chloride channel openers, and a vehicle.

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Murad is applied as discussed above. The reference further teaches that the composition can be administered orally, intravenously, and topically. Suspensions, solutions and aerosols are taught as composition forms. The reference lacks an exemplification of intravenous or topical administration or solution composition forms. See Col. 8, line 43-Col. 9, line 21.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify the compositions of Murad as topical or intravenous a) because Murad teaches topical, intravenous, and oral administration as interchangeable and equivalent; and b) because of the expectation of achieving a method of specifically targeting areas to be treated.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify the compositions of Murad in the forms of solutions a) because Murad teaches tablet forms and solutions as interchangeable and equivalent; and b) because of the expectation of achieving a composition that can easily be topically applied.

Claims 30, 78, 79, 80, 81, 84-89 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad as applied to claims 22, 23, 26, 29, 31-32, 39-44, 49-55, 58, 71-74 and 77 above, and further in view of Breton et al. (6,224,850).

Murad is applied as discussed above. The reference does not teach chloride channel openers.

Breton et al. teach that wrinkles can be reduced by administering composition comprising chloride channel openers. See Col. 2, line 38-Col. 3, line 30.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the chloride channel openers taught by Breton et al. into the composition of Murad because of the expectation of achieving a composition with enhanced anti-wrinkle effects.

Claims 35, 36, 37, 38, 45, 46, 47, 48, 56-57, 75, 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad et al. as applied to claims 22, 23, 26, 29, 31-32, 39-44, 49-55, 58, 71-74 and 77 above, and further in view of Hahn (WO 96/19182).

Murad is applied as discussed above. The reference fails to teach preferred salt forms of manganese.

Hahn teaches compositions comprising manganese for cosmetic application. Chloride, gluconate, acetate, sulfate, and others are taught as preferred anions accompanying manganese. See abstract; page 16, line 18-page 17, line 9.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the manganese salts taught by Hahn for manganese ascorbate because of the expectation of achieving similar cosmetic effects from manganese.

Claims 82, 83, 90, 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad in view of Breton et al. as applied to claims 22, 23, 26, 29-32, 39-44, 49-55, 58, 71-74, 77, 78-81, 84-89 and 92 above, and further in view of Hahn (WO 96/19182).

Murad and Breton et al. are applied as discussed above. The references do not teach preferred salt forms of manganese.

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Hahn teaches compositions comprising manganese for cosmetic application. Chloride, gluconate, acetate, sulfate, and others are taught as preferred anions accompanying manganese. See abstract; page 16, line 18-page 17, line 9.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the manganese salts taught by Hahn for manganese ascorbate taught by the combined references because of the expectation of achieving similar cosmetic effects from manganese.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-

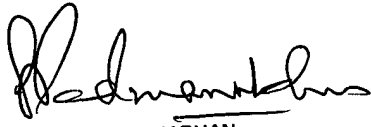
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1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
May 5, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER
5/5/03